COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF ENVIRONMENTAL AFFAIRS
DEPARTMENT OF ENVIRONMENTAL PROTECTION

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Summary of and Response to Comments on the Air Quality Proposal for Biotech
9/22/05

General Comments: The Department received a diverse range of comments on this proposal. Supportive comments included suggested changes that would make the exemption and permit by rule available to a broader subset of industry. One commenter suggested additional reporting requirements. Several comments were generally critical of exempting from plan approval any VOC emissions from this industry.

310 CMR 7.02(2)(b)(33) Exemption from Plan Approval for Biotechnology Laboratories

Comment: Several commenters were concerned with the unconditional exemption from plan approval requirements that was proposed for VOC emissions from biotechnology laboratories. (Environmental League of Massachusetts, Health Care Without Harm, Sciencecorps, Toxic Action Center)

Response: This amendment codifies what is currently the regulatory context for biotech laboratories. As explained in the background document, emissions from laboratories tend to be very low, far less than 1 ton per year, and therefore, are not subject to plan approval under existing regulations. It is highly unlikely that emissions from a laboratory would ever rise to a level that would cause the Department to impose a permit or controls. Biotechnology laboratories are still required to track emissions for the purposes of calculating facility-wide emissions. This information is available to DEP should there ever be a need to further examine laboratory emissions.

Comment: Laboratories should be more broadly defined to cover both research that is not yet aligned with a specific FDA application and exploratory research conducted at a college or university. Two definitions were offered; the OSHA definition and the definition in use for New England Universities Laboratory XL Rule. (Nexus Environmental Partners)

Response: The focus of this amendment is biotech manufacturing facilities and laboratories that support them, not basic research labs. As a practical matter, however, basic research labs, whether they are in companies or universities, generally emit such small amounts of VOC that they would not be subject to air plan approvals under existing regulations.

310 CMR 7.03(25) Conditional Exemption for Biotechnology Surface Disinfection Processes

Comment: The amendments to the air pollution control regulations should be made available to medical device manufacturers whose products are regulated by FDA but are not based on living systems. (DePuy) Similarly, the exemption should be made available to companies that make these FDA regulated products using synthetic chemistry processes rather than processes based on living systems. (EPIX Pharmaceuticals)

Response: The MassDEP is working with the Office of Technical Assistance to identify any appropriate regulatory improvements for the medical device industry. The change will not be made at this time, however the Department will consider this request in its work with OTA. At the same time, the feasibility of extending this exemption to companies that use synthetic chemistry as the basis for their production will be evaluated.

Comment: In response to the Department's request concerning acetone usage in the industry, it was suggested that the exemption be revised to allow for emission of non-criteria air pollutants from operations such as glass cleaning by inserting the following: "7.03(25)(b)3. The total facility-wide actual emissions, including new or modified surface disinfection processes, shall not exceed 5 tons of non-criteria air pollutants per 12-month rolling period. This non-criteria air pollutant emission limitation includes all process operations from the facility. In addition, facility-wide actual emissions of non-criteria air pollutants shall not exceed 1.0 tons per calendar month." (Massachusetts Biotechnology Council)

Response: The Department is very interested in the information that will be forthcoming through a survey that MBC is conducting on acetone usage by its members. With this information, MassDEP will consider proposing an amendment to the air regulations for biotech that would provide an exemption from plan approval for acetone use. To expand the exemption beyond acetone to other specific non-criteria air pollutants would require further research and additional rulemaking that is not contemplated by the Department at this time.

Comment: EPA is concerned that the proposed regulation may not satisfy the criteria that "…where the coverage is optional, [it must] provide for notice to the permitting authority of a source's election to be covered…" (Environmental Protection Agency)

Response: Pursuant to section 7.03(5), a person required to file source registration under section 7.12 (e.g. a person owning, operating or controlling a facility with non-combustion federal

potential to emit (PTE) equal to or greater than 10 tons per year of organic material) is required to report any construction, substantial reconstruction or alteration undertaken pursuant to section 7.03 on the next required source registration. This amendment, 310 CMR 7.03(25), establishes federal PTE at 15 TPY of VOC and 10 TPY of HAPs. Therefore, an owner or operator is required to notify MassDEP of their election to comply with the requirements of this amendment.

In addition, the amendment would require a new biotech facility that would otherwise be a major source, either:

- be issued a plan approval pursuant to 310 CMR 7.02(4) (Limited Plan Application) or 7.02(5) (Comprehensive Plan Application), or
- comply with the requirements 310 CMR 7.03(25) – Biotechnology Surface Disinfection Processes.

Compliance with one of the above is not optional, but required. Therefore, we believe EPA's suggestion to require further notification to the Department is not necessary.

Comment: It is recommended that the required method for calculating actual emissions be clarified. (Environmental Protection Agency)

Response: Existing section 310 CMR 7.03(6) Record-keeping requires facilities to keep sufficient records of the amount of VOC and HAP materials used to document emission rates. Facilities calculate emission based on the assumption that all VOC or HAP content of any materials used is emitted. If a facility wishes to take credit for VOC or HAP material as not being emitted because it is either reclaimed or sent off site for disposal, the facility must keep sufficient records to demonstrate this. The Department believes that further clarification is not needed.